IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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IN RE: PROPECIA (FINASTERIDE) PRODUCTS LIABILITY LITIGATION	:	Master File No. 1:12-md-02331 -BMC-PK
	:	MDL No. 2331
This Document Relates to: ALL CASES	:	Honorable Brian M. Cogan
	:	Magistrate Judge Peggy Kuo

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April 19, 2016

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Confidential videotape deposition of CYNTHIA GROSSEL SILBER, M.D., taken pursuant to notice, was held at the law offices of Morgan, Lewis & Bockius LLP, 1701 Market Street, 18th Floor, Philadelphia, Pennsylvania, beginning at 8:14 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

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that -- how did you learn how to interpret this data? Where did you learn that skill?

A. I learned how to look at data from my medical training; and specifically postmarketing data, I learned when I joined Merck. I was trained by my colleagues in management.

Q. So to the extent that you were evaluating data from an epidemiological perspective, that was all on-the-job training; correct?

A. I would not say that I was evaluating data from an epidemiologic perspective.

Q. What is a safety signal?

A. A safety signal is the combination of a product and an adverse event that may represent an association between the two or may not.

Q. In a given patient population; correct?

A. Not necessarily.

Q. Well, you have users of a

particular drug. Right?

A. Well, if that's your sense. You can't have a combination of an adverse event with a drug without having the population defined as those people who take the drug.

Q. So you are in effect studying the outcome of a particular drug on a patient population; correct?

(Pause.)

THE WITNESS: But that was -- yes, but that was not the -- the extent of that work.

BY MR. BECKER:

Q. And that study of the outcome of a drug on a patient population is the hallmark of epidemiology, is it not?

MR. HARRELL: Object to form.

THE WITNESS: I don't know what the hallmark of epidemiology is.

BY MR. BECKER:

Q. It's a form of epidemiology; correct?

A. I don't know.

Q. Do you know what epidemiology is?

A. I can't give you a definition.

Q. As a medical doctor, have you ever heard the term epidemiology?

A. Yes, I have.

Q. What's your understanding of that term?

A. My understanding of that term is that it is the science of the study of populations.

Q. So let's go back to where we started. If you didn't have any formal training in epidemiology, to the extent you were studying a patient population at Merck related to the use of Propecia, all that knowledge came from on-the-job training; correct?

A. No, not all that knowledge came from on-the-job training.

Q. Where did you get it then beyond --

A. I --

Q. -- at Merck?

A. No, a lot of the knowledge that we use comes from our past medical training.

Q. Like what?

A. Like knowledge about disease states, knowledge about drug use, knowledge about medical conditions.

Q. But it's fair to say you have no formal education in epidemiology or the study of patient populations; correct?

MR. HARRELL: Object to form.

THE WITNESS: I do not have a degree in epidemiology.

BY MR. BECKER:

Q. Did you ever take any courses in epidemiology?

A. Yes, I did.

Q. How many?

A. One.
Q. How many credits?
A. It was in medical school. There are no credits in medical school.
Q. So like a semester or a year --
A. Uh-hum.
Q. -- or a quarter?
A. Yes.
Q. Which one?
A. I believe it was a semester.
Q. So your formal education regarding the study of epidemiology is one semester of study for one class in medical school; correct?
A. That is my formal education.
Q. Go back to your resume, if you would.
A. Yes.
Q. Well, let me ask you a question about that: Because you have relatively little formal education in epidemiology, you understand that signals can be calculated to a numerical value;

correct?

MR. HARRELL: Object to form.

THE WITNESS: Signals can be calculated in different ways. It depends upon the source of the data.

BY MR. BECKER:

Q. One of those is a numerical value; correct?

A. I -- I don't know to what you're referring. I can't answer a general question like that.

Q. Okay. If -- you have an understanding, though, that signals can be calculated; correct?

A. Again, I don't know to what type of data you're referring.

Q. Well, when you're looking for a particular safety signal, what are you looking for?

A. We're looking for evidence that the particular adverse event either is related to the drug or is not.

Q. And how do you calculate that or how do you quantify it?

A. We do not necessarily quantify it. It depends on the data source.

Q. Let's take Propecia, for example.

A. Uh-hum.

Q. Okay? One of the adverse events that's been alleged in this case is that sexual dysfunction can continue after discontinuation of the drug.

You have an understanding of that; correct?

A. Yes.

Q. So how would you quantify whether or not the data that Merck has in its possession does or does not demonstrate a safety signal?

MR. HARRELL: Object to form.

Go ahead.

THE WITNESS: If you are asking for quantification, the

place I would go would be the clinical trial data.

BY MR. BECKER:

Q. What if you wanted to -- but you can evaluate safety signals not just based on clinical trial data. Right?

A. Yes, but it's much more difficult to quantify and I thought that's what we were discussing.

Q. I am. So I'm asking you, if you were going to look at a drug safety profile over time, from launch to today, how would you quantify that?

A. I would go to the clinical trial data.

Q. And that's all you would look at. You wouldn't look at any --

A. For quantification, that's the best data.

Q. Would you defer -- you're not claiming to be an epidemiologist; correct?

A. I am not.

Q. As a person -- you don't

claim your expertise is in epidemiology; correct?

A. Correct.

Q. Would you defer to the testimony of -- or to the findings of epidemiologists regarding safety signals over your own?

A. I would work with an epidemiologist on my team.

Q. Okay. But would you ultimately defer to their calculations and computations, quantifications over your own?

A. I would need to see a specific example.

Q. Let's go back to your resume. Directing you to bullet point number 1 on page 7 under "Major Responsibilities at Merck Research Laboratories," it says, "Signal detection and safety surveillance for multiple marketed products and for products currently in development."

Do you see that?

A. Yes, I do.

Q. My questions, by the way, throughout the deposition, unless I direct you otherwise, are going to be solely related to Propecia and Proscar. Okay?

A. Yes.

Q. Can we have that understanding?

A. Yes.

Q. Okay.

What -- in terms of your work on Propecia, what does bullet point -- or number 1 reference or refer to?

A. Can you be a bit more specific?

Q. Yeah, what did you do to, quote, unquote, engage in signal detection and safety surveillance for Propecia?

A. I participated in the processes that we have at Merck that were extant at the time for postmarketing signal detection and postmarketing data

oversight.

Q. And what does that mean?

A. That means that I was responsible for the oversight of the interpretation -- but not by myself. I was part of a team that oversaw the interpretation of the postmarketing data that Merck received from Propecia.

Q. So let's see if we have some areas of agreement here. A safety signal can identify an association between a drug and a particular outcome. Do you agree with that?

A. It can.

Q. So, for example, you could have a safety signal based on the clinical trial data and the postmarketing reports that Merck received establishing an association between Propecia and persistent sexual dysfunction; correct?

I'm not saying that one exists, but you could -- you could reach that conclusion.

MR. HARRELL: Object to

form.

Go ahead.

THE WITNESS: It would be very difficult to reach the conclusion from postmarketing data.

BY MR. BECKER:

Q. All I'm asking you is this: You can evaluate -- when looking at to determine whether or not a safety signal exists, you're evaluating data to see if an association exists between a drug and a particular outcome; correct?

A. Yes.

Q. So you could evaluate data to look at whether or not Propecia is associated with persistent sexual dysfunction; correct?

A. We can evaluate reports of patients on Propecia who have persistent erectile dysfunction. Whether or not we can come to any firm conclusions is highly dependent on the type of data that we have.

Q. So that is a, yes, you could evaluate that question based on the data you have; correct?

MR. HARRELL: Object to form.

THE WITNESS: No, that is that I could evaluate the data.

MR. BECKER: I'm ask -- that's all I'm asking.

THE WITNESS: Okay.

BY MR. BECKER:

Q. You could look at a given data set --

A. Uh-hum.

Q. -- and evaluate whether that data set has enough information in it to establish an association between Propecia and a negative outcome; correct?

A. I'm sorry. Could you repeat the question?

Q. Sure.

Merck has certain adverse events that it receives once a drug is launched in the community; correct?

A. Correct.
Q. And it chronicles those adverse events as they come in in realtime. True?
A. Yes.
Q. And part of your job is to evaluate those adverse events as they come in over time; correct?
A. Yes.
Q. And part of the reason you're evaluating those adverse events is to determine whether or not there is an association between an alleged adverse event and the particular drug that you're looking at; correct?
A. Yes.
Q. And you use that postmarketing data to reach the conclusion of yes, maybe, or no. Right?
A. We use that postmarketing data as part of a larger package of data. We don't often use the postmarketing data in a vacuum.
Q. Now, when you refer to in

bullet point 1 here on your resume of signal detection and safety surveillance -- do you see that?

A. Uh-hum.

Q. -- what did you specifically do to determine whether or not there was a safety signal related to an association between Propecia and persistent sexual dysfunction following discontinuation of use?

A. Whether there was a signal?

Q. Yes.

A. Is that the question?

Q. No. The question is, what did you do to determine whether or not a signal existed?

A. When I picked up the product, the issue was already one that was under ongoing analysis in the program, so I did not do signal detection for this particular adverse event.

Q. So let me make sure I totally have that clear. So from whatever the date was, whether it was

2006 or '7 or '8 or whenever you joined the Propecia team, is it your testimony you never engaged in signal detection related to Propecia and persistent ongoing sexual dysfunction?

A. I engaged in signal evaluation. The signal had been identified by the time I joined the program. It had already been reviewed.

Q. So let me go back and get a sense what that means. Are you saying that there was a signal that was identified between Propecia and persistent sexual dysfunction prior to your joining the team?

A. Prior to my joining the team, there was investigation of that product-event combination, yes.

Q. And what was the outcome?

A. The outcome when I joined the team was that persistent erectile dysfunction was not causally associated with Propecia.

Q. So there was no signal by

the time you -- when you joined the team, the view of Merck was that there was no signal establishing an association between Propecia and persistent ongoing sexual dysfunction following discontinuation of use?

A. I don't think I would say there was -- there had been a signal and we were following it on an ongoing basis.

Q. Okay. So that --

A. It's a product-event combination. That's all it is.

Q. I get that. A signal, just so -- let's make it clear for the jury --

A. Uh-hum.

Q. -- a signal does not equate to causation. Right?

A. Correct.

Q. But a signal is, like, if you were to -- if you're building a puzzle, okay, you got lots of pieces in the puzzle. Right?

A. Uh-hum.

Q. Yes?

A. Yes.
Q. You got the border and then you got the inner parts. Right?
A. Yes.
Q. And the puzzle has a picture. Right?
A. Yes.
Q. And you're trying to figure out what that picture is by putting those pieces together. Right?
A. Yes.
Q. And a signal is a piece of the puzzle that might lead to a conclusion that a particular outcome is causative; correct?
MR. HARRELL: Object to form.
THE WITNESS: I'm sorry. I don't follow your analogy.
BY MR. BECKER:
Q. A signal might establish an association between a drug and a negative outcome; correct?
MR. HARRELL: Object to

form.

THE WITNESS: A signal is the beginning of the process of evaluation.

BY MR. BECKER:

Q. Right. It's one piece in the puzzle. Right? As you try and build this picture to get to whether or not the drug causes a particular outcome. True?

MR. HARRELL: Object to form.

Go ahead.

THE WITNESS: I'm sorry. I'm just not -- I'm not following the analogy.

BY MR. BECKER:

Q. Okay. Well, let me make sure I understand what you're saying clearly. Had Merck identified a signal -- I'm not asking if they agreed that it was causative or not, but prior to your arrival, when you joined the Propecia team, had Merck identified a signal existed between Propecia and ongoing

sexual dysfunction following discontinuation of use?

A. Yes.

Q. And you joined the team sometime in the 2007-2008 timeframe to the best of your recollection?

MR. HARRELL: Object to form; asked and answered.

BY MR. BECKER:

Q. Let me put it this way: You joined the team well before 2012; correct?

A. Yes.

Q. And Merck did not amend its label in the United States to tell men about the association, this signal you had identified, between Propecia and persistent ongoing sexual dysfunction following discontinuation of use until April of 2012; correct?

A. I --

MR. HARRELL: Object to form.

THE WITNESS: -- object to

the -- I object to the word association.

BY MR. BECKER:

Q. Okay. Well, you don't get the right to object. You get to answer my questions and your lawyer gets to object --

A. Well --

Q. -- so I'll ask you again: You testified earlier that somebody had established a signal between Propecia and persistent ongoing sexual dysfunction prior to you joining the team in the mid 2000s; correct?

A. Yes.

Q. And it would take another four, five, six years till that signal was indicated in the warning label here in the United States; correct?

MR. HARRELL: Object to form.

Go ahead.

THE WITNESS: I was not objecting in a legal sense to the

use of the word association.

So I would say a couple of things. I would say --

MR. BECKER: Stop. I'm -- no, no, no --

MR. HARRELL: She gets to answer her question.

MR. BECKER: No, she gets to answer the question that I asked.

MR. HARRELL: You can't cut her off while she's answering.

MR. BECKER: But then she gets to answer -- I don't have a judge here so I can't stop her as nonresponsive.

MR. HARRELL: I'm sorry, but you asked a question and she's answering.

MR. BECKER: I asked a yes/no question.

MR. HARRELL: You let her answer the question.

MR. BECKER: I'm going to withdraw the question.

BY MR. BECKER:

Q. When was the first time that the United States warning label discussed a potential signal between -- a potential association between persistent ongoing sexual dysfunction following discontinuation of use and Propecia?

A. I believe it was between the end of 2010 and the beginning of 2011.

Q. There was a warning label -- you have an understanding that Merck put in a CBE regarding erectile dysfunction in 2011; correct?

A. Yes.

Q. And you have an understanding that the FDA amended the language from Merck's CBE and expanded it to sexual dysfunction in 2012. True?

A. Yes.

Q. And that was the first time that this potential association was discussed in the United States warning label; correct?

A. Yes.

MR. HARRELL: Object to form.

THE WITNESS: Yes.

BY MR. BECKER:

Q. Let me go back to your resume for just one other quick second. Bullet point number 2 indicates, "Analysis of safety signals and development of strategic response to safety issues for both marketed products and products in development."

Do you see that?

A. Yes, I do.

Q. As it related to Propecia, what did you do to analyze the safety signal?

A. We followed the Merck procedures that were in place at the time that consisted of review of individual reports, review of aggregate data, and review of literature on the subject.

Q. And what, if anything, was the outcome of that analysis?

A. With regard to --